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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,593	11/29/2001	Seiji Sakano	KP8447DIV	2953

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,593

Applicant(s)

SAKANO ET AL.

Examiner

Prema M Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 96 is/are allowed.
- 6) ☒ Claim(s) 88, 92-95, 97 is/are rejected.
- 7) ☒ Claim(s) 89-91 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-87 have been canceled on 2/24/2004. New claims 88-97 (2/24/2004) are under consideration.

2. Receipt of Applicant's arguments and amendments filed on 2/24/2004 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 1/2/04:

- (i) the objection to the title of the invention; and
- (ii) the objection to the abstract of the invention.

4. Applicant's arguments filed on 2/24/2004 have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 88, 90-95, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for suppressing differentiation of undifferentiated blood cells in vitro comprising contacting said cells in vitro with a polypeptide of amino acid sequence of SEQ ID NO:5, 6 or 7, thereby suppressing differentiation of said cells, does not reasonably provide enablement for a method for suppressing differentiation of undifferentiated blood cells in vitro comprising contacting said cells in vitro with a serrate-1 peptide as recited in claim 88. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With respect to claims 88 and 92 as recited, what is claimed in the instant invention broadly encompasses "all" serrate-1 peptides. However, the specification is only enabling for the human serrate-1 proteins as set forth in the specification on page 11, first full paragraph:

The amino acid set forth in SEQ ID NO: 5 is a sequence of the active center of the present invention of human Serrate-1 minus the signal peptide (corresponding to an amino acid No. 1 to 198 in SEQ ID NO: 7 of human Serrate-1 of the present invention. The amino acid sequence in SEQ ID NO: 6 is the amino acid sequence of extracellular domain of the present invention of human Serrate-1 minus the signal peptide, and corresponds to an amino acid No. 1 to 1036 in SEQ ID NO: 7 of the mature full length amino acid sequence of human Serrate-1 of the present invention. The amino acid sequence of SEQ ID NO: 7 is the mature full length amino acid sequence of the human Serrate-1 of the present invention.

The specification is non-enabling for the unlimited number of proteins, which are encompassed by the scope of the claims. Claim 88 is a single means claim (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: "A single means claim, i.e. where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph." (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). Since no material limitations for the protein have been recited in the claim and only a biological activity has been recited, the claim encompasses every conceivable structure (means) for achieving the stated property (result), a

Art Unit: 1646

fact situation comparable to Hyatt. The claimed invention encompasses compositions not envisioned or described in the specification, and neither does the specification disclose how these claimed compositions could be distinguished from each other. The specification only enables a human serrate-1 proteins comprising the amino acid sequences shown in SEQ ID NO:5, 6, and 7, the polypeptide having specific characteristics and properties. These properties may differ structurally, chemically and physically from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which other nucleic acids encoding these proteins are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little, thereby rendering the results of the assays taught in the specification unpredictable (see pages 47-54, Examples 10-13). Therefore, it would require undue experimentation to determine which proteins having the biological activity of a human serrate-1 protein, would be encompassed by the scope of the claims. The disclosure of a single natural polypeptide is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims, which encompass every and all serrate-1 polypeptides, including mutants thereof. In In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his

Art Unit: 1646

work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Furthermore, the amount of embodiments corresponding to the desirable compositions, may be innumerable, and the enabled embodiments amount to only those of SEQ ID NO:5-7. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe a method of using any other serrate-1 polypeptides other than those whose amino acid sequences are shown in SEQ ID NO:5-7, and since it is deemed to constitute undue experimentation to determine all the others, the disclosure is not commensurate with the scope of the claims. Therefore, Applicants are not enabled for a method for suppressing differentiation of undifferentiated blood cells in vitro, comprising contacting said cells in vitro with polypeptides having anything less than the amino acid sequence shown in SEQ ID NOS:5-7. It is suggested that by employing conventional claim

Art Unit: 1646

language, the claims be amended to include the specific polypeptides supported by the instant specification.

Claim rejections-35 USC § 112, second paragraph

7. Claims 92-95 and 97 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 92 and 97 recite "gene", which is incorrect because a gene is a smallest inheritable unit under study responsible for the transmission of genetic material from one generation to another. There is no clear definition of "gene" provided in the specification. However, the specification recites the DNA encoding the specific human serrate-1 polypeptides (see pages 7-8). It is suggested that the claims be amended to recite the specific DNA (SEQ ID NO 1) encoding the serrate-1 polypeptide.

Claims 93-94 are rejected under 35 U.S.C. § 112, second paragraph, insofar as they depend on claim 92 for the "gene" limitation.

Conclusion

Claim 96 is allowable.

Claims 89-91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1646

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.

Application/Control Number: 09/995,593

Page 7

Art Unit: 1646

Primary Examiner

Art Unit 1646

March 11, 2004